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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

SHELLEY FAVOURS,

Plaintiff,

vs.

KONINKLIJKE PHILIPS, N.V.; PHILIPS
NORTH AMERICA, LLC; and PHILIPS
RS NORTH AMERICA, LLC,

Defendants.

No.

COMPLAINT FOR DAMAGES

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1 Plaintiff, Shelley Favours, brings this personal injury case for damages and
 2 Demands a Jury trial based on her use of now recalled assisted breathing medical devices
 3 designed, marketed, promoted, manufactured, distributed, and sold by defendants
 4 Koninklijke Philips, N.V., Philips North America, LLC, and Philips RS North America,
 5 LLC (collectively “Philips” or “Defendants”). Plaintiff brings this suit based on her
 6 medical and emotional injuries caused by this admittedly defective device and asserts
 7 claims for: (1) Failure to Warn; (2) Design Defect, Strict Liability; (3) Negligent Failure to
 8 Warn; (4) Negligent Design Defect; (5) Negligent Recall; (6) Breach of Express Warranty;
 9 (7) Breach of the Implied Warranty of Merchantability; (8) Arizona Consumer Fraud Act
 10 (AZ. Rev. Stat. §§ 44-1522, *et seq.*); and (9) Unjust Enrichment.

11 I. INTRODUCTION

12 1. This action arises from the personal injuries Plaintiff, Shelley Favours
 13 suffered as a result of using defendants Continuous Positive Airway Pressure (“CPAP”)
 14 breathing machine.

15 2. In 2017, Plaintiff was prescribed and starting using her CPAP machine for
 16 sleep apnea. She used the machine nightly, for at least eight hours, until 2021.

17 3. Sleep apnea is a dangerous condition in which an obstruction in the throat
 18 causes a person to stop breathing for a brief period while sleeping. At best, the condition
 19 causes daily fatigue and restlessness. At worst, sleep apnea can seriously impede the flow
 20 of oxygen resulting in brain damage or death.

21 4. In CPAP therapy, a machine delivers flow of air through a mask over the
 22 nose or mouth, which increases air pressure in the throat, so the airway does not collapse
 23 during inhalation. CPAP therapy assists breathing during sleep and successfully treats sleep
 24 apnea.

25 5. Since using the CPAP machine, Plaintiff has been diagnosed with stage II
 26 ductal carcinoma, and has undergone substantial treatment including a lumpectomy and
 27 radiation. In addition, she has suffered emotional distress as a result of her debilitating
 28 health issues.

1 6. Philips was responsible for the design, marketing, manufacture, post-
2 marketing surveillance, sale, advertising, promotion, warning, and distribution of a variety
3 of CPAP and Bi-Level Positive Airway Pressure (“BiPAP”) devices for patients with
4 obstructive sleep apnea. Philips also manufactures, markets, imports, sells, and distributes
5 a variety of ventilator devices subject to the recall.

6 7. On June 14, 2021, Philips voluntarily recalled 3-4 million of these sleep
7 apnea machines and mechanical ventilators (“Recalled Medical Devices”) in the United
8 States. *See* Recall Notice attached as **Exhibit A**.

9 8. The recalled medical devices contain polyester-based polyurethane (“PE-
10 PUR”) foam for sound abatement. Philips announced that this foam may break down and
11 be inhaled or ingested. Critically, the PE-PUR foam may emit volatile compounds
12 (“VOCs”) that may be inhaled, ingested, adversely affect organs and are carcinogenic.
13 Philips announced these hazards could result in “serious injury which can be life
14 threatening or cause permanent impairment.”

15 9. In its, recall announcement Philips advised its customers to discontinue use
16 of their affected CPAP and BiPAP devices, and it instructed mechanical ventilator patients
17 to continue treatment until they are able to consult with their physicians. Phillips also
18 recognized that CPAP and BiPAP customers may have to continue using their devise due
19 to “lack of alternatives,” and that “alternate ventilator options for therapy may not exist or
20 may be severely limited for patients who require a ventilator for life sustaining therapy, or
21 in cases where therapy disruption is unacceptable.”

22 10. Philips knew about these very substantial and material risks long before the
23 recall. Patients who used the Recalled Breathing Machines have complained about black
24 particles in their machines for several years, including Plaintiff Shelley Favours. When she
25 started using her CPAP device for sleep Apnea in July of 2017, she was not aware of the
26 harm these particles would cause. Philips did not warn the public or its customers about
27 these hazards until late April 2021 and did not initiate a recall until June 14, 2021.
28

1 Shockingly, absent this litigation, Philips had no plan to replace or repair any of the affected
2 devices.

3 11. In fact, Philips timed its recall of the Recalled Breathing Machines to
4 coincide with the launch of its next generation of products, which purportedly do not suffer
5 from the same PE-PUR foam issues. Thus, the only safe option that Philips offers to
6 Plaintiff is to purchase Philips' newer model, thus profiting Philips further.

7 12. Consequently, Plaintiff now faces an impossible choice. She needs her CPAP
8 machine to breath, but Philips has told her that further use of her device is dangerous. She
9 could purchase a new device without PE-PUR foam, but these machines are in limited
10 supply and very expensive. Despite the immediacy of the issue, Philips has only made
11 vague promises of a future "recall and replacement" program, without giving any of its
12 customers new devices, money to buy new devices, or even direction on how to self-
13 remedy the PE-PUR foam defect.

14 II. JURISDICTION AND VENUE

15 13. This Court has subject matter jurisdiction pursuant to under 28 U.S.C.
16 § 1332, diversity jurisdiction. The amount in controversy exceeds \$75,000.

17 14. Venue is proper in this District under 28 U.S.C. § 1391 because Philips has
18 a principal place of business in this district; Philips has marketed, advertised, sold, and
19 leased its products within this District; and many of the acts and transactions giving rise to
20 this suit occurred in this District, including manufacturing, promotion, marketing,
21 distribution, and sale of CPAP/Bi-PAP devices.

22 III. PARTIES

23 A. Plaintiff

24 15. Plaintiff Shelley Favours is an adult resident of Arizona and citizen of
25 Flagstaff, Arizona. Flagstaff, Arizona is located in Coconino County.

26 16. In 2017, Plaintiff was prescribed a DreamStation CPAP device in Flagstaff,
27 Arizona by Dr. Martha Barlow.
28

1 17. On September 30, 2020, Plaintiff obtained a new DreamStation CPAP device
2 in Flagstaff, Arizona.

3 **B. Defendants**

4 18. Koninklijke Philips, N.V. is a Dutch multinational company headquartered
5 in Amsterdam, Netherlands, and is the parent company of Philips North America, LLC and
6 Philips RS North America, LLC.

7 19. Defendant Philips North America, LLC is a Delaware company with its
8 principal place of business in Cambridge, Massachusetts.

9 20. Defendant Philips RS North America, LLC (formerly Respironics, Inc.) is
10 Delaware company headquartered in Pittsburgh, Pennsylvania.

11 **IV. STATEMENT OF FACTS**

12 **A. Plaintiff's Injuries.**

13 21. On July 21, 2017, Plaintiff Shelley Favours was prescribed a CPAP device
14 by Martha Barlow, NP at Northern Arizona Healthcare. She was prescribed the device
15 because she was experiencing sleep apnea. She used the device nightly for the next three
16 years to treat her condition. On September 30, 2020, she received a new CPAP machine.
17 She used this device until July 14, 2021 when she was notified of the CPAP recall.

18 22. Plaintiff hoped CPAP therapy would be an effective treatment for her sleep
19 apnea. However, after using the devices daily for four years, she began experiencing
20 serious health conditions. Specifically, she was diagnosed with a ductal carcinoma.
21 Plaintiff underwent significant treatment, including a lumpectomy and radiation. In
22 addition, Plaintiff experienced headaches, inflammation, and sinus issues.

23 23. The knowledge and information about the dangers disclosed by Philips in the
24 *Urgent Medical Device Recall* were unknown, available, or knowable to Plaintiff before
25 June 14, 2021. This lawsuit is therefore timely and brought within the prescribed
26 limitations period based upon legal principles of accrual, discovery, and tolling.

B. Philips Marketed Its Defective Breathing Devices.

24. Philips, through its RS (formerly Respironics) and Philips NA subsidiaries, manufactures and sells several lines of CPAP machines, BiPAP machines and mechanical ventilators. Philips markets these products as “Sleep & Respiratory Care,” part of its “Connected Care” segment of business. In 2020, Sleep & Respiratory Care accounted for 49% of Philips’ total worldwide Connected Care sales. Philips has sold approximately two million Defective Breathing Devices in the United States and 3-4 million total devices worldwide.

25. Philips markets these devices as safe and effective. For example, Philips’ website says that its DreamStation CPAP and BiPAP machines “empower users to embrace their care with confidence, and enable care teams to practice efficient and effective patient management.” Philips has advertised its ventilation products as “effective and affordable.”

26. Philips does not mention in any of its marketing, advertising, labeling or instruction materials that the foam in the Defective Breathing Devices may degrade and pose a serious health threat to users.

27. Philips’ CPAP, BiPAP, and mechanical ventilator products are very expensive, costing up to thousands of dollars in retail price.

C. Philips Recalled Its Defective Breathing Devices.

28. Philips’ first public admission of trouble with these devices came in its Q1 2021 quarterly report on April 26, 2021. Under the innocuous heading “Regulatory Update,” Philips disclosed for the first time that “user reports and testing” indicated “that there are possible risks to users related to the sound abatement foam used in certain of Philips’ sleep and respiratory care devices currently in use.” Philips admitted that “the foam may degrade under certain circumstances,” but it did not specify the risks from this degradation. Philips did not issue a recall at this time.

29. Nearly two months passed without a public update. Finally, on June 14, 2021, Philips issued a “voluntary recall notification.” In this notification, Philips admitted that there were two dangerous conditions at issue: the potential that PE-PUR foam “may

1 degrade into particles which may enter the device's air pathway and be ingested or inhaled
2 by the user"; and the possibility that the PE-PUR foam "may off-gas certain chemicals"
3 (also known as "Volatile Organic Compounds," or "VOCs"). This notification warned that
4 the PE-PUR foam degradation can cause "headache, irritation, inflammation, respiratory
5 issues, and possible toxic and carcinogenic effects"; and that VOCs from the foam can
6 cause "headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and
7 carcinogenic effects."

8 30. In this document, Philips also provided further information about the risks
9 from VOC exposure. Philips stated, "VOCs are emitted as gases from the foam included
10 in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse
11 health effects." The VOCs emitted by the PE-PUR foam at unsafe levels include "Dimethyl
12 Diazine" and "Phenol, 2,6- bis (1,1-dimethylethyl)-4-(1-methylpropyl)." These VOCs
13 "may cause irritation and airway inflammation," something which Philips admitted may
14 be particularly grave for patients with underlying lung diseases or reduced
15 cardiopulmonary reserve."

16 31. Notably, Philips did not recall its DreamStation 2 CPAP machines, which it
17 released in 2020. The DreamStation 2 line of products do not have PE-PUR foam
18 insulation. This fact raises an inference that Philips knew prior to its April 26 and June 14,
19 2021 notices that the PE-PUR foam was dangerous to its respirator and ventilator users.

20 **D. Philips Understands the Danger Posed by the PE-PUR Foam Defect.**

21 32. Despite its understated rhetoric, Philips understands the risk at which it put
22 its customers.

23 33. Philips instructed its CPAP and BiPAP users to "[d]iscontinue use" of their
24 machines. Nevertheless, recognizing that many patients have a "lack of alternatives" to
25 their Defective Breathing Device, customers were directed to "consult with your physician
26 to determine if the benefit of continuing therapy with your device outweighs the risks
27 identified in the recall notification."
28

34. Although the PE-PUR foam defect is no less dangerous for customers who use mechanical ventilators, Philips has not instructed them to stop using their devices due to the “lifesustaining” nature of ventilation therapy. Once again, Philips understands that “alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified.

E. Philips Has Not Provided Its Customers with Replacement Devices or Refunds.

35. Philips’ so-called “recall” does not actually provide Plaintiff with a new CPAP device, but again suggests consumers can buy the next generation of its product. As Philips’ June 14, 2021 announcement makes clear:

Repair and replacement program Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.

As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips’ recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.

36. Thus, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacement foam.

37. At the same time, Philips intends to profit from the so-called recall by selling more of its next generation product, the DreamStation 2. Philips intentionally timed the recall to coincide with the launch of the DreamStation 2.

1 54. The design of the Recalled Breathing Machines, including, but not limited
2 to, design, manufacturing, and use of the PE-PUR foam and the placement of the foam
3 within the Recalled Breathing Machines, was defective and unreasonably dangerous,
4 causing degradation and inhalation of the PE-PUR foam, and causing economic injuries,
5 as well as ductal carcinoma, headaches, inflammation, sinus issues, and exposure to
6 materials with toxic and carcinogenic effects.

7 55. The design of the Recalled Breathing Machines and the PE-PUR foam
8 rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their
9 intended purpose.

10 56. The dangers of the Recalled Breathing Machines outweighed the benefits and
11 rendered the products unreasonably dangerous. Indeed, there are other CPAP and other
12 machines that do not use a similarly toxic foam that is subject to degradation, inhalation,
13 and ingestions.

14 57. Upon information and belief, Defendants knew of the defective nature of the
15 Recalled Breathing Machines but continued to design, manufacture, market, and sell them
16 so as to maximize sales and profits at the expense of public health and safety.

17 58. Safer, alternative machines from other manufacturers were available that did
18 not suffer from the defect as set forth herein and that did not have an unreasonable risk of
19 harm as with the Recalled Breathing Machines and their unsafe PE-PUR foam.

20 59. The risk benefit profile of the Recalled Breathing Machines was
21 unreasonable, the products should have had stronger and clearer warnings or should not
22 have been sold in the market.

23 60. At all times material, Recalled Breathing Machines were expected to reach,
24 and did reach, users and/or consumers across the United States, including Plaintiff, without
25 substantial change in the defective and unreasonably dangerous condition in which it was
26 sold.

COUNT IV

NEGLIGENT DESIGN DEFECT

70. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein.

71. Under Arizona law, manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

72. Defendants negligently designed the Recalled Breathing Machines. Philips owed Plaintiff a duty to design the Recalled Breathing Machines in a reasonable manner. The design of the Recalled Breathing Machines, including, but not limited to, the design of the PE-PUR foam and the placement of the PE-PUR foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, causing economic injuries, as well as ductal carcinoma, headaches, inflammation, sinus issues, and exposure to materials with toxic and carcinogenic effects.

73. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

74. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

75. Safer, alternative machines from other manufacturers were available that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe foam.

76. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

- D. The Full amount of Plaintiff's punitive damages;
- E. Exemplary damages to the full extent allowed by law;
- F. The full amount of Plaintiff's damages for loss of consortium;
- G. Plaintiff's attorneys' fees and costs;
- H. Prejudgment interest on Plaintiff's damages; and
- I. Such other and further relief the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

1 DATED: December 13, 2021

Respectfully submitted,

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